# CME Article

# Rapid Diagnostic Testing for HIV

## Clinical Implications

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There have been many advances in HIV counseling, testing, and referral over the past ten years. One of the most recent advances is the United States Food and Drug Administration's (FDA) approval of a rapid test. As a result of the availability of rapid diagnostic testing for HIV, practices regarding testing and counseling need to be updated, particularly in time-sensitive situations in which rapid results are crucial.

### LEARNING OBJECTIVES

I. To recognize the clinical role of rapid diagnostic HIV testing.
II. To understand the role of rapid diagnostic testing to reduce the risk of vertical HIV transmission.
III. To define when preliminary rapid diagnostic HIV test results can be given to the physician and the patient.

### INTRODUCTION

The HIV/AIDS epidemic has had a profound impact on New Jersey, which is fifth in the United States in cumulative reported AIDS cases (43,009 cases through December 2001), leads the nation in the percentage of women reported with AIDS (28%), and ranks third in the nation with 788 reported cumulative pediatric AIDS cases. Almost all pediatric AIDS cases (94%) and pediatric HIV cases (94%) in New Jersey are a result of vertical HIV transmission.[1]

The major focus of HIV prevention and control has been to promote the acceptance of risk-reducing behaviors through prevention counseling and testing and to facilitate linkage to medical, prevention, and other support services.[2] Testing has played a major role in the prevention of HIV transmission. There have been many changes in testing since the development of the original enzyme immunoassays and western blot. At the forefront of recent advances is the FDA approval of a rapid diagnostic HIV test.

Several developments have focused increased interest on rapid HIV testing. The most important is the availability of effective combination antiretroviral therapy that can improve the quality of life and longevity of persons infected with HIV. The use of antiretroviral agents during pregnancy, even starting as late as labor, has significantly reduced vertical HIV transmission. In addition, people who know they are infected with HIV are more likely to practice risk-reduction behavior.

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## Clinical Role

The use of rapid tests in clinical care settings can substantially improve the delivery of HIV counseling and testing (CT) services, because patients can receive their results the same day. This is highly significant considering that the Centers for Disease Control and Prevention (CDC) reported that of the two-and-a-half million people tested in 1995, 25% of those testing positive and 33% of those testing negative did not receive their test results. With fifty-eight thousand people tested in 2000, New Jersey mimics the national statistics with 25% and 33% of those testing positive and negative, respectively, at publicly funded CT sites, not returning for their test results.[3] The CDC calculated that a total of 697,495 more people nationwide would have learned their HIV status if rapid testing had been used.[4]

In addition, rapid testing plays a crucial role in time-sensitive decisions about the need for prophylaxis to reduce transmission in cases of occupational exposures and women presenting in labor with unknown HIV serostatus.[5, 6]

### The New Jersey Standard of Care

In New Jersey, it is required that all pregnant women receive HIV counseling and be offered voluntary HIV testing (*New Jersey Administrative Code* 8:61-3.1). This includes women who present in labor with unknown HIV status.

A published report indicates that 25% of HIV-infected women in New Jersey do not receive prenatal care,[5] and these are not the only women to present in labor with unknown HIV serostatus. Some women may have previously refused testing and some women may not have received their HIV test results. The use of rapid testing is necessary to further reduce perinatal transmission of HIV. For many women, the first and only chance for HIV counseling and testing is when they present in labor. Hence, in order to make intrapartum treatment a potential intervention for women who present in labor with unknown HIV status, voluntary HIV rapid or expedited diagnostic testing is vital.

Voluntary HIV screening for pregnant women who present in labor with unknown HIV status is cost-effective because, for each child born uninfected as a result of this screening, it is estimated that $8,900 is saved for every year of that child's life.[7] Because there is such a limited opportunity to prevent HIV transmission to the baby, preliminary positive results can be used to guide the need for short-course therapy that reduces the risk of mother-to-child HIV transmission. The regular nonrapid testing takes a week to get results, which is too late to prevent transmission. For routine prenatal visits, the nonrapid testing with final confirmation can be done, and then women can be offered antiretroviral agents starting at fourteen weeks gestational age and an elective C-section can be planned, if the viral load is >1000.

The New Jersey Department of Health and Senior Services (DHSS), in collaboration with ad hoc advisory committees comprised of stakeholders, developed a statewide approach to reducing the risk of vertical HIV transmission. The stakeholders included obstetricians, pediatricians, nurses, consumers, HIV counselors, hospital administrators, laboratory directors, infection-control professionals, and representatives from professional societies and organizations. This approach states that a woman who presents in labor with the delivery team unaware of her HIV status, like all pregnant women in New Jersey, should receive counseling and be offered HIV testing (*New Jersey Administrative Code* 8:61-3.1). Laboratories may then provide either rapid or expedited HIV testing. The testing can be done within the hospital or can be sent out to another facility. However, the results should be available as soon as possible, but no longer than twenty-four hours after the specimen is obtained.

If the result is positive, the woman should be offered short-course antiretroviral therapy in an effort to reduce the risk of vertical HIV transmission. For their follow-up care, HIV-positive mothers and HIV-exposed newborns should be referred to physicians with experience and expertise in treating HIV disease.

The New Jersey DHSS and the National Pediatric and Family Hiv Resource Center are collaborating

to disseminate information about the statewide approach. This broad approach includes designing a counseling session for women in labor, conducting train-the-trainer sessions for hospital-based counseling of women in labor, providing technical assistance to hospitals in updating their policies and procedures, developing written educational material, providing continuing medical education, and evaluating the implementation and effectiveness of this statewide approach.

## Rapid Diagnostic Hiv Tests

The results of rapid tests to detect HIV antibody are available in about ten minutes, thus enabling health care providers to supply definitive negative and preliminary positive results to patients at the time of testing, or shortly after. In comparison, results from the enzyme immunoassays (EIAs) currently used for HIV screening are often not available for one or two weeks.[4]

Over sixty types of rapid HIV tests are being used throughout the world.[2] However, only three rapid tests, the Single Use Diagnostic System for Hiv 1 (SUDS), manufactured by Abbott, OraQuik, manufactured by Orasure Testing Technologies, Inc., and Reveal, manufactured by MedMira, are currently FDA approved for use in the United States.

The sensitivity and specificity of rapid assays are comparable to those of non-rapid EIAs (100% sensitivities and >99% specificities). Because HIV prevalence is low in most United States testing settings, the negative predictive value of a single rapid test is high. Hence, a negative rapid test does not require further testing and negative results with result-specific counseling can be provided to most people at the initial visit. However, because the positive predictive value varies with the prevalence of HIV infection in the population tested, the positive predictive value will be low in populations with low prevalence.[8] Therefore, a reactive rapid test must be confirmed by a supplemental test.[9] In studies conducted outside the United States, specific combinations of two or more rapid HIV assays have provided results as reliable as those from the EIA–western blot combination that is currently in widespread use.[10] However, this is not available for use in the United States, since only one rapid test is FDA approved for commercial use. Many national organizations, including the CDC and the National Alliance of State and Territorial AIDS Directors are encouraging the FDA to fast-track approval of rapid HIV tests.[2, 10] When additional rapid tests become available for use in the United States, the Public Health Service will re-evaluate algorithms using specific combinations of two or more rapid tests for screening and confirming HIV infection.

To use the rapid test, high-quality testing must be provided. The laboratory must institute rigorous quality control and quality assurance plans, including participation in proficiency testing.[4]

### Reporting Results

The CDC and the Association of State and Territorial Public Health Laboratory Directors (ASTPHLD) conducted a workshop in Atlanta on October 24, 1997, to discuss rapid HIV testing, the potential health benefits and risks in reporting provisional rapid test results, and the feasibility of changing the recommendations of the Public Health service and ASTPHLD for reporting HIV test results. Workshop participants agreed that it is optimal to follow the 1989 United States Public Health Service Algorithm for HIV testing, which recommends confirmatory test results before reporting reactive HIV test results in order to minimize the risk of reporting false-positives.[8] However, they agreed that exceptions are warranted when the health benefit of reporting HIV rapid test results offsets the potential risk of reporting false-positive test results (e.g., patients who fail to learn their HIV status because they do not return to receive their test results). Rapid HIV tests also can assist health care providers who must make immediate decisions about initiating HIV prophylaxis, such as when caring for health care workers after occupational exposure and for pregnant women in labor who have not been tested or whose results are not available.[4]

The Public Health Service recommends that people whose rapid test results are reactive should be counseled about their likelihood of being infected with HIV before confirmatory results are

available, but they must be vigorously encouraged to return for definitive results. This recommendation is based on research that demonstrates that those who receive preliminary results understand the meaning of the result and prefer rapid testing.[11]

## HIV Counseling with the Rapid Test

The CDC is currently conducting a study, RESPECT 2, to determine whether providing a rapid HIV test, the result of the test, and counseling in one clinic visit is as effective at prevention of sexually transmitted diseases (STDs) as having the standard HIV testing with the result and second counseling session one to two weeks after the test. The study builds on information gained during the project RESPECT study, which showed that patients who are given HIV tests and two counseling sessions one to two weeks apart have fewer STDs during the following year than do those who are tested and only receive educational messages without counseling.[12] However, the study emphasized that many of those tested for HIV do not receive the full benefit of risk-reduction counseling, because they do not return for their HIV test results and the second counseling session. Consequently, rapid testing provides the opportunity for more tested patients to take advantage of risk-reduction counseling.

By maximizing the opportunities for risk-reduction counseling, particularly in those patients who do not return for their results, rapid testing can have a profound impact on the prevention and control of HIV transmission. Counseling patients about the likelihood that their result reflects a true HIV infection should emphasize the importance of confirmatory testing. The post-test counseling can include phrases such as, "a good chance of being infected" or "very likely infected."[11] When giving the rapid test results, the prevalence of HIV and an assessment of each patient's individual risk should be incorporated in the discussion.[4]

## Conclusion

Rapid diagnostic HIV testing is beneficial to improve the proportion of patients who receive their test results, to help with clinical decision making about the use of short-course anti-retroviral therapy to reduce the risk of vertical HIV transmission for women who present in labor with unknown HIV status, and to help determine the need for post-exposure prophylaxis for potential occupational exposures to HIV.[5,6] As HIV counseling, testing, and referral advances, it is imperative that adjustments be made in recommendations and practices. *NJM*

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CME EXAMINATION: DEADLINE SEPTEMBER 30, 2004

## "Rapid Diagnostic Testing for HIV"

1. For which of the following can preliminary positive rapid diagnostic HIV tests be given?
   A. Index patient to whom a health care worker had a needlestick exposure
   B. Injection drug user who presents for a routine office visit
   C. Patients presenting to an HIV counseling and testing site
   D. Patient who presents with symptoms of a sexually transmitted disease

2. Which of the following patients should be provided counseling and offered a rapid diagnostic HIV test to reduce the risk of transmission?
   A. Man who presents with a sexually transmitted disease
   B. Routine office visit for a patient with a history of injection drug use
   C. Ward clerk on a unit that has an HIV infected patient
   D. Woman in labor with unknown HIV status

3. Which of the following should be included in the post-test counseling session for a patient with a preliminary positive rapid diagnostic HIV test?
   A. Information on additional laboratory tests (i.e.viral load and CD4 T cell tests)
   B. Obtaining a list of contacts who need to be informed of their potential HIV exposure
   C. Referral to a physician with experience and expertise treating HIV disease
   D. Their likelihood of being infected with HIV before confirmatory results are available

4. Which of the following is an advantage of rapid diagnostic HIV testing?
   A. Increases the likelihood that a patient will seek HIV counseling and testing
   B. Increases the number of patients who receive their HIV results
   C. Increases the proportion of HIV-infected patients who enter treatment
   D. Increases adherence to antiretroviral therapy in HIV-infected patients

5. Which test can be used to confirm a preliminary positive HIV diagnostic rapid test?
   A. A western blot HIV confirmatory test
   B. Another enzyme immunoassay (EIA)
   C. Repeat testing with the same brand of rapid test
   D. Viral load polymerase chain reaction test

## Answer Sheet

### "Rapid Diagnostic Testing for Hiv"

Darken the correct answers

1. [A] [B] [C] [D]
2. [A] [B] [C] [D]
3. [A] [B] [C] [D]
4. [A] [B] [C] [D]
5. [A] [B] [C] [D]

Time spent reading this article and completing the learning assessment and evaluation: _____hours _____minutes

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